PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

FITZPATRICKS
4 West Regent Street
Glasgow G2 1RS
GRANDE BRETAGNE

DP 16/01

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	13/01/2004
Applicant's or agent's file reference: 32/43/64087WO	**REPLY DUE** within 1 / 00 months/days from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB03/01404	31/03/2003	02/04/2002

International Patent Classification (IPC) or both national classification and IPC

A61K47/10

Applicant

NORBROOK LABORATORIES LIMITED et al.

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV [ ] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [ ] Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 02/08/2004

Name and mailing address of the IPEA:

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D-80298 Munich
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Authorized officer

Examiner

Formalities officer
(incl. extension of time limits)
Tel. (+49-89) 2399 2828

I. Basis of the opinion

1. The basis of this written opinion is the application as originally filed.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability

1. In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claims references).

2. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 34 (2) (b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report. The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

NB: Should the applicant decide to request detailed substantive examination, then an international preliminary examination report will normally be established directly. Exceptionally the examiner may draw up a second written opinion, should this be explicitly requested.

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To:

FITZPATRICKS
4 West Regent Street
Glasgow G2 1RS
GRANDE BRETAGNE

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	16.03.2004
Applicant's or agent's file reference: 32/64087CO	**REPLY DUE** **within 2 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/01404	31.03.2003	02.04.2002

International Patent Classification (IPC) or both national classification and IPC
A61K47/10, A61K47/10

Applicant
NORBROOK LABORATORIES LIMITED et al.

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is:

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Formalities officer (incl. extension of time limits)
Hutterer, G
Telephone No. +49 89 2399-8066

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-21 filed with telefax on 22.01.2004

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-21

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-21 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☒ the claims, or said claims Nos. 1-21 are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	
Inventive step (IS)	Claims	1-21
Industrial applicability (IA)	Claims	

2. Citations and explanations

   see separate sheet

SECTION III .....

1. According to the wording of Article 6 PCT the **claims** shall define the matter for which protection is sought, they must be clear and concise and shall be fully supported by the description.

   Independent product claims 1, 9, 14, 16 and 20 as well as independent method claims 17 and 21 do not meet the requirements of Article 6 PCT with respect to conciseness.

   Although the above claims have been drafted as separate independent claims, they appear to relate effectively within each category to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness.

   Moreover, lack of clarity of the claims as a whole arises by such a wording of claims, since the plurality of independent claims in each category makes it difficult to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

2. Furthermore, an objection could also be based on Article 5 in combination with Article 6 PCT in that respect that the applicant, whilst claiming all ways of achieving the desired result of the claimed subject-matters has provided support and disclosure for only a small number of definite ways, eg claiming a product comprising carprofen in almost any concentration (see present claim 9) and any poloxamer whilst showing in the Examples only embodiments comprising carprofen in one concentration and applying only Lutrol^{R} F68 as the poloxamer. Which means that the subject-matter is neither supported nor disclosed over its whole breadth.

SECTION V. .....

A preliminary evaluation of the requirements of Article 33 PCT is possible despite the deficiencies as mentioned under SECTION III., above.

1. Reference is made to the following documents:

D1: EP-A-0 955 063
D2: CH-A-663 788
D3: US-A-5 283 067

2. The present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matters of the independent product claims 1, 9, 14, 16 and 20; and independent method claims 17 and 21 do not involve an inventive step (Rule 65(1)(2) PCT).

The presently claimed product, ie the aqueous composition comprises in certain amounts

- carprofen

and

- a poloxamer.

Such products differ from products disclosed in eg D1 only by the fact that the compound carprofen has not explicitly been mentioned. However, D1 clearly stated that anti-inflammatory compounds can advantageously be used in combination with poloxamers to arrive at products solving to same problem, ie the provision of injectable aqueous compositions, as presently defined. Carprofen is well known to the person skilled in the art as being such a compound and its substitution in the products according to D1 must be considered obvious, this the more, as eg D2 suggests its usability for anti-inflammatory purposes. The person skilled in the art gets furthermore the information from D3 that injectable aqueous compositions comprising poloxamers and anti-inflammatory agents can successfully be prepared to solve exactly the same problem. The claimed subject-matter lacks therefore an inventive step.

It is noted that the Comparative Examples as presented in the description on page 8, fall under the wording of present independent product claims.

Essentially, the dependent claims specify certain carprofen salts which are known from D2, or define the poloxamer which can be taken from eg D1, and indicate that further components can be present. To arrive at these embodiments the person skilled in the art can take corresponding information from D1, thus any inventive step must also be denied for the dependent claims.

3. The amendments filed with the International Bureau under Article 19(1) introduce

probably subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. Neither the functional statement relating to claim 2 nor the x/y/z values of 98/67/98 as defined in claims 3 and 18 could not be found in the originally filed documents.

4. Claims 20 and 21 comprise references to the description, ie to Examples. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

5. Taking into account the above, it is not at present apparent which part of the application could serve as a basis for a new claim which would satisfy the criteria set forth in Article 33(1) PCT. Should the applicant nevertheless regard some particular matter as suitable an independent claim including such particular matter should be filed taking account of Rule 6.3(b) PCT. The applicant should also indicate in the letter of reply the difference vis-à-vis the state of the art and the significance thereof.

   In order to expedite the proceedings relating to the present application it is however considered necessary to determine whether the requirements of inventive step are satisfied in the light of the cited documents D1 - D3 and the general knowledge of the person skilled in the art. Reference is made to the PCT Preliminary Examination Guidelines, Chapter IV, item 8 (particularly with respect to the evaluation of an inventive step).

   It should be noted that any argument given with respect to an inventive step can only be considered if reflected by technical features in the wording of the independent claim(s).

   Functional features in a product claim are not suited to replace technical features in order to establish improved capabilities of the product per se. If a subject-matter shows different properties or different capabilities then such effects must be attributable to some specific technical features which have not been considered in the prior art.

   In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of

the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

The applicant is requested to file amendments by way of replacement pages. He should also take into account the requirements of Rule 66.8 PCT.

Possibly, a specific new embodiment of subject-matter already disclosed might provide unexpected advantages or surprising effects over the pertinent prior art. If so, the applicant should give convincing arguments or should furnish evidence, most preferably by filing test results as a comparison with the closest prior art (eg D1).

To meet the requirements of Rule 5.1(a)(ii) PCT, the documents D1 - D3 should be identified in the description and the relevant background art disclosed therein should be discussed.

The description must be brought into conformity with amended claims; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed, Article 34(2)(b) PCT.

In order to expedite proceedings and in view of the short time available under PCT procedures, the applicant should ensure that in the reply it is dealt with all issues raised in this written opinion. According to Rule 66.4 PCT the International Preliminary Examination Authority is entitled to issue only one preliminary opinion.